Clinical Cross-over Trial, testing Dynamic Air Mattresses

Assessment of pressure injury risk and mattress functionality

NCT number: NA
Sunnaas Rehabilitation Hospital, Departments of Spinal Cord Injury, Multi-trauma, Neurology and Burns,
January 1st 2022

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

The PROJECT'S purpose, and why you're a potential candidate

This is a request, whether you would like to participate in a clinical trial of two dynamic air mattresses. One of the mattresses are in daily use at the hospital (control mattress), whilst the other is a newly developed automatic turning mattress (intervention mattress).

We are asking persons with a newly acquired spinal cord injury, neurological diseases or multi trauma that might causesequelae related to paralysis and/or loss of sensibility, to participate in this project, due to the fact, that you are at risk of developing pressure injury related complications. If risk of such complications is to occur, actions to relieve the pressure from the exposed body area is required. Development of pressure injury while being in the acute phase rehabilitation after your injury or disease, could increase the length of hospitalization, and could result in future need of long-lasting follow-up at the outpatient wound clinic.

In the present project, we will compare two mattresses and map out their differences in terms of pressure injury development, sleep quality, pain, quality of life and mattress comfort. In addition, we will study strain and satisfaction in the staff when using the two mattresses.

What does the project require from you?

We want to give you information and ask whether you would like to participate in the project. The assessments will be performed in the middle of your stay. Participation includes testing two different mattresses, one being the mattress in daily use at the hospital (control mattress), the second being the new mattress we would like to test (intervention mattress). Because most of our patients are given the control mattress at admission, you will start with using the intervention mattress, and then return to the control mattress after seven days of testing the intervention mattress. However, reverse use may occur. Thus, your participation in the project will last for a total of two weeks. One week per mattress. A nurse will check up on you every morning and evening, and make an evaluation of the condition of your skin. Before and after using each mattress, you will be presented with questionnaires related to sleep quality, experienced quality of life, pain and comfort of being bed rested on the mattress. The time estimate to complete the questionnaires ranges from 20 to 25 minutes. In addition two of the participants, together with two of the nurses will be asked to participate in an interview to further collect information regarding consumer experiences. The interview will last a maximum of 30 minutes. Participation in the project will not affect the rehabilitation treatment you will receive otherwise. In advance of inclusion in the project, additional pressure assessments of you lying on the mattresses will be performed. This is to ensure that participation will be safe for you, due to knowledge of pressure risk limits. If the assessed pressure deviates from the pre-set values, the testing will be terminated.
We will register some of the information written in your medical record. This is information, such as gender, age, height, weight and some details regarding your injury/disease. In addition known pressure injury risk factors, depression before injury/disease, heart disease, thromboembolic diseases, diabetes mellitus, kidney disease, incontinence, and use of stimulants, as well as prescribed medication during the participation.

Potential advantages and disadvantages

Your health is in no way at risk during the project. You will be examined twice a day during the participation period, and at first sign of negative deviation from the expected result, your participation will be terminated, due to increased risk of having a pressure injury if you continue the testing.

Vouluntairy participation with the ability to quit at any given moment

Participation in the project is voluntary. If you want to participate, you sign the letter of consent at the final page. You can at any given moment, and without explanation, cancel your participation in the project. Doing so will not have any consequences for you nor your acute rehabilitation treatment. Should you withdraw from the project, all continuous research will be performed without using your personal information. The pressure assessments is performed without your name linked to the results. You have the ability to demand all data regarding your participation to be deleted within 30 days. This demand does not account for any information of the study that has been published.

The project initiates September 2021 and concludes in December 2022.

What will happen to your personal information?

The personal information provided will only be used in agreement with the project's purpose. Any extended usage and storage of information can only occur after being approved by the Norwegian Data and Privacy Protecting Agency (NSD). You have a right to know about any stored information related to you. This also includes the right to adjust any information you deem as incorrect. All data is stored in a looked, fireproof cabinet, or at the hospitals privacy secured research area. You're entitled to any information related to the security measures utilized in keeping your personal information secure. If you have any complaints regarding the security measures, don`t hesitate to contact the data inspectorate.

All information will be handled without using names, date of births or other information that could be used to identify any of the patients. A code will be used to connect you to your information through the usage of a list of names. The list is secured in a looked, fireproof cabinet. Only the project leader Ingebjørg Irgens has access to this list.

Publishing of the results of the project is a necessary part of the process. All published material will take measures to leave all participants anonymous. We guarantee complete anonymity.

Your information will be stored for 15 years after the project concludes due to control considerations. Then the information will be anonymized and deleted.

Insurance

You will be ensured through the hospitals insurance policy. In addition to this, the standard ruleset for patient injuries also applies.

Economy

The project is involved in the hospitals engagement towards the development and testing of new technology/equipment. The company that are developing the intervention mattress is funding the study Parts of this investment will be used in relation to technical equipment and various resources required. The research group performing the project consists of professional`s staff members and

researchers from Sunnaas Rehabilitation hospital. The developers of the intervention mattress has ownership of the data procured from the pressure assessments. The members of the project group will write a research article without any influence from the mattress developers. However, some of the funding will pay for analysing the data procured, the writing of the article, and the publishing of the results.

Approval

The intervention mattress is approved by Statens Legemiddelverk (the Norwegian Medicine Agency (SLV/NO918491775/0941-55297), and conforms to the European Regulation 2017/745, with a risk class 1 as per rules in Annex VIII.

The project is approved by the Norwegian Data Privacy Agency 19th April 2021. A Risk- and Vulnerability analysis has been performed, and the intervention mattress is approved, by the Data Protection Ombud at Sunnaas Rehabilitation Hospital.

The regional Committee for Regional Committees for Medical and Health Research Ethics (REK) (Ref. **229188, 15.01.21) and the Norwegian Medicines Agency have evaluated the project and concluded that the trial won't require any further supervision from REK.**

Sunnaas Rehabilitation hospital's administrative director Einar Magnus Strand has the main responsibility for making sure that the patients' rights are followed, project leader Ingebjørg Irgens is responsible on a daily basis.

Contact information

Should you have any further questions or want to withdraw from the project, please contact:

Project leader Ingebjørg Irgens, e-mail: Ingebjorg.Irgens@sunnaas.no.

If you have any questions related to the privacy regulations related to the project, please contact the Data Protection Ombud at Sunnaas Rehabilitation Hospital, Jan Robert Ernstsen,

email: jaerns@sunnaas.no.

Datatilsynet - personvern og informasjonssikkerhet | Datatilsynet

I CONSENT TO PARTICIPATING IN THE DESCRIBED PROJECT BASED ON THE WRITTEN AND WERBAL INFORMATION I HAVE RECEIVED

Location and date	Participant`s signature (piston signature will be accepted)
	Participant`s name in capital letters
	If necessary, legal guardian`s name in capital letters if participant is not able to sign

I hereby confirm having provided all relevant information regarding the project

Location and date	Signature
	Role in the project